

REMARKS

Reconsideration and withdrawal of the rejections made in the mentioned Office Action are respectfully requested, in view of the foregoing amendments and the following remarks.

Summary of Amendments

By the foregoing amendments claim 1 is canceled and claims 33 and 41 are amended, whereby claims 22-46 are pending in the present application. Claims 22, 33, 41 and 42 are independent claims.

It is noted that the cancellation of claim 1 (and of claims 2-21 canceled previously) is without prejudice or disclaimer to the prosecution of these claims in one or more divisional and/or continuation applications.

Summary of Office Action

Claims 22-46 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 1 and 22-41 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to

P21961.A05

enable one skilled in the art to make and/or use the invention.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Youichirou et al., JP 10/130153 A.

Response to Office Action

Reconsideration and withdrawal of the rejections of record are respectfully requested.

Response to Rejection under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 22-46 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection asserts that the present specification does not show any methods of treating at least one of diabetes and complications arising from diabetes in a subject in need of such treatment with a mixture of polylactic acids having a condensation degree of 3 to 19, a method of preventing diabetes in a subject with the mixture, a method of preventing complications arising from diabetes with the mixture or a method of reducing the blood sugar level in a subject with the mixture.

Applicants respectfully traverse this rejection as unfounded for at least the following reasons. What the rejection essentially alleges is that when reading the present specification it appears to one of skill in the art that at the time of filing the present application the

inventors did not yet anticipate that the recited mixture of polylactic acids could be used to treat/prevent diabetes and/or complications arising from diabetes, or reduce the blood sugar level in a patient. It is respectfully submitted that in view of, in particular, pages 10-13 of the present application and the detailed description and discussion therein of the experiments conducted with diabetes-induced mice and the successful reduction of the blood sugar level, the Examiner's position is untenable.

In this regard, the Examiner's attention is directed, in particular, to the following passages of the MPEP:

2163.02 Standard for Determining Compliance With the Written Description Requirement The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its

limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was “ready for patenting” such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by “whatever characteristics sufficiently distinguish it”). The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement. If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. This conclusion will result in the rejection of the claims affected under 35 U.S.C.112, first paragraph -description requirement, or denial of the benefit of the filing date of a previously filed application, as appropriate. See MPEP § 2163 for examination guidelines pertaining to the written description requirement. (Emphases added)

2163.04 Burden on the Examiner with Regard to the Written Description Requirement The inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant’s disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97. (Emphasis added)

I. STATEMENT OF REJECTION REQUIREMENTS In rejecting a claim, the examiner must set forth express findings of fact which support the lack of written description conclusion (see MPEP § 2163 for examination guidelines pertaining to the written description requirement). These findings should: (A) Identify the claim limitation at issue; and (B) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. A general allegation of “unpredictability in the art” is not a sufficient reason to support a rejection for lack of adequate written description. A simple statement such as “Applicant has not pointed out where the new (or amended) claim is supported, nor does there appear to be a written description of the claim limitation ‘ ____ ’ in the application as filed.” may be sufficient where the claim is a new or amended claim, the support for the limitation is not apparent, and applicant has not pointed out where the limitation is supported. When appropriate, suggest amendments to the claims which can be supported by the application’s written description, being mindful of the prohibition against the addition of new matter in the claims or description. See *Rasmussen*, 650 F.2d at 1214, 211 USPQ at 326. (Emphasis added).

In the present case, the application as filed provides not only substantially literal support for claims 22-46 of record (e.g., in the original claims 1-7 and in numerous passages of the specification), but even contains experimental results which clearly show that the present inventors were in the possession of ample evidence which demonstrated the suitability and effectiveness of a mixture of polylactic acids having a condensation degree of 3 to 19 for the claimed purpose. In this regard, the discussion of the test results summarized in Table 1 at pages 12 and 13 of the present specification may, in particular, be referred to. It is not seen what more the present inventors could have done in order to convey that they were in possession of the claimed invention.

In view of the foregoing, it is submitted that withdrawal of the lack of written

P21961.A05

description rejection of the present claims under 35 U.S.C. § 112, first paragraph is warranted, which action is respectfully requested.

Response to Rejection under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 1 and 22-41 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. In particular, the Examiner takes the position that the instant application does not contain any test results or experimental data showing the instant medicament will, in fact, prevent diabetes or diabetes complications especially in a mammal not presently at risk of or predisposed to developing such a disease.

Regarding the declaration under 37 C.F.R. 1.132 submitted on January 24, 2003, the rejection alleges that this declaration only shows results of a subject with moderately high blood sugar level. The rejection acknowledges that the declaration shows that the instant mixture is used to prevent any further complications or prevent the reoccurrence of the diabetes or diabetes complications in a subject already having the disorder. The Examiner suggests to amend the present claims by inserting the phrase “in need thereof” to overcome the rejection.

As suggested by the Examiner, independent claims 33 and 41 have been amended by reciting therein the phrase “in need thereof”. Independent claim 22 already contains a corresponding recitation. Claim 1 has been canceled. It is pointed out that this amendment

P21961.A05

is not to be construed as Applicants' acquiescence to the rejections; rather, the amendments to claims 33 and 41 have been proposed merely in order to expedite the issuance of the patent.

In view of the foregoing, withdrawal of the lack of enablement rejection of claims 22-41 under 35 U.S.C. § 112, first paragraph is respectfully requested.

Response to Rejection under 35 U.S.C. § 102(b)

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Youichirou et al., JP 10/130153 A. Since claim 1 has been canceled, this rejection is moot. It is pointed out, however, that the cancellation of claim 1 should not be construed as Applicants' admission that the Examiner's corresponding arguments are of any merit. Rather, claim 1 has been canceled merely in order to expedite the issuance of the patent.

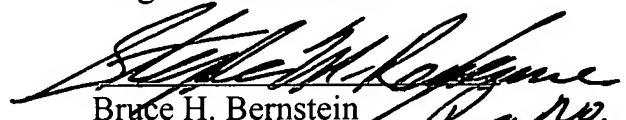
P21961.A05

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested.

The undersigned will contact the Examiner by telephone on or about November 20, 2003 to discuss any issues which may yet have to be resolved.

Respectfully submitted,
Shigeo TAKADA et al.


Bruce H. Bernstein
Reg. No. 29,027

31,296

November 10, 2003
GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191